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May 24, 2004

Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building, 1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460



Subject: Comments on the HPV Test Plan for Phosphoric acid, mono (2-ethylhexyl) ester, compound with tert-dodecanamine

Dear Administrator Leavitt:

The following comments on ACC HERTG's test plan for the chemical Phosphoric acid, mono (2-ethylhexyl) ester, compound with tert-dodecanamine are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

ACC HERTG submitted its test plan on December 17, 2003, for the chemical Phosphoric acid, mono (2-ethylhexyl) ester, compound with tert-dodecanamine (CAS No. 67763-14-8). This compound, also referred to as mono-alkyl phosphate ester tertiary alkyl amine salt, is used as a petroleum additive in petroleum base stocks where it is combined with di-alkyl phosphate ester tertiary alkyl amine salts to formulate automotive and industrial gear oils. Finished automotive gear oils will contain only 0.24-0.9 wt% mono-alkyl phosphate ester tertiary alkyl amine salt while finished industrial gear oils will contain even less, 0.06-0.3 wt%. ACC HERTG has submitted a poorly documented test plan that lacks any detail and merely proposes testing for each of the 17 SIDS endpoints in the HPV program. For each endpoint, the sponsor simply states that adequate data were not located and testing will be conducted, with no mention of the OECD protocol ACC HERTG plans to use for evaluation of these endpoints. At the very least, we would like to ensure that if testing is conducted, protocols employ the minimum number of animals.

Although available data for physicochemical properties, environmental fate, ecotoxicity, and human health effects for this chemical may be limited, it is alarming that ACC HERTG proposes to conduct animal studies before even establishing the physicochemical and environmental fate properties of Phosphoric acid, mono (2-ethylhexyl) ester, compound with tert-dodecanamine. For example, physical/chemical properties could indicate potential for the material to be corrosive or caustic. Such properties could then be verified by a nonanimal method, such as Corrositex ™, EpiDerm ™, EpiSkin ™, etc. Testing of caustic materials in animals is generally precluded by the difficulty in

differentiating toxicity from direct corrosive effects. If the sponsor does, in fact, conduct testing for fish toxicity, acute mammalian toxicity, and repeated dose/reproductive/developmental toxicity according to OECD protocols, 802-815 animals will be killed.

We strongly urge ACC HERTG to first establish the physical and chemical properties of this chemical, such as water solubility and octanol/water partition coefficient, as well as hydrolysis data, before conducting studies in animals. We would also suggest that the sponsor review existing data for the chemical 2-ethyl hexyl phosphate (CAS No. 12645-31-7), as data for this chemical may be used to bridge data gaps for the sponsored chemical. There is no indication that this possibility was evaluated by ACC HERTG.

We believe this test plan demonstrates the failure of the HPV program to foster a thoughtful analysis of the likely toxicity of a chemical. Instead, it merely serves as a checklist approach to toxicology where new information obtained via animal studies may not be useful or relevant for hazard assessment. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 327, or via e-mail at *meven@pcrm.org*.

Sincerely,

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Research Analyst

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Director of Research